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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,699	12/30/2003	Terry B. Strom	13985-057002	9466
26161	7590	04/19/2006	EXAMINER	
FISH & RICHARDSON PC			HAMUD, FOZIA M	
P.O. BOX 1022			ART UNIT	
MINNEAPOLIS, MN 55440-1022			PAPER NUMBER	

1647

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/749,699

Applicant(s)

STROM ET AL.

Examiner

Fozia M. Hamud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/30/03; 08/23/04; 01/30/06</u> | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Status of Claims/Amendments:

1. The preliminary amendment filed on 12 December 2003 has been entered. Claim 1 has been amended and claims 2-34 have been cancelled. Thus claim 1 is pending and is under consideration by the Examiner.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted 12 December 2003, 23 August 2004 and 30 January 2006 have been received and comply with the provisions of 37 CFR §§1.97 and 1.98. They have been placed in the application file and the information referred to therein has been considered as to the merits.

Claim rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2a. Claim 1 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 of the instant Application is drawn to a therapeutic composition comprising a first agent that targets an interleukin 15 receptor (IL-15R) and a second agent that targets an interleukin 2 receptor (IL-2R). However, the specification as filed

Art Unit: 1647

does not describe the structure of said agents. Therefore, conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention.

To satisfy the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998). Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. Adequate written description requires more than a mere statement that it is part of the invention. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In the instant case, Applicant is claiming a first agent that targets an interleukin 15 receptor (IL-15R) and a second agent that targets an interleukin 2 receptor (IL-2R), however, Applicants do not provide the structure of any of said agents.

The instant specification discloses that one of the embodiments of the instant invention is a combination of IL-2 and IL-15 antagonists, (pages 2-3). However, the instant specification does not provide a description of the structure of the claimed composition. The instant specification teaches the structures of IL-15 and IL-2, and that IL-15 would target IL-15R while IL-2 would target IL-2 receptor. However, the specification does not describe the structure of a therapeutic composition that comprises an agent that targets IL-15R as well as an agent that targets IL-2R. One of ordinary skill in the art would not be able to visualize the claimed composition.

Therefore, it does not appear that the inventors were in possession of a first agent that targets an interleukin 15 receptor (IL-15R) and a second agent that targets an interleukin 2 receptor (IL-2R).

2b. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is drawn to a therapeutic composition comprising a first agent that targets an IL-15R and a second agent that targets an IL-2R. However, the specification, does not teach how to make or use said therapeutic composition.

The specification teaches and is also well known in the art that IL-2 and IL-15 utilize heterotrimeric receptors that include cytokine specific private IL-2R α and IL-15R α , respectively, and shared IL-2 β and IL-2 γ chains, (see top of page 2). Therefore, the instant specification speculates that blocking this receptor might have therapeutic

Art Unit: 1647

benefits since both IL-2 and IL-15 are detected during immune activation in vivo.

However, the instant specification does not disclose a therapeutic composition which comprises an agent that targets IL-15R and one that targets IL-2R, neither does the specification teach how these components can be attached together.

The criteria set forth in *Ex parte Forman* (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant application, due to the large quantity of experimentation to design a therapeutic composition which comprises the recited agents and screen said composition for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the unpredictability of the effects of therapeutic agents which necessitates the performance of proper controls to ensure efficacy and safety, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Conclusion

3. No claim is allowed.

Advisory Information

Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
12 April 2006



EILEEN B. O'HARA
PRIMARY EXAMINER